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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR CONFIRMATION NO. APPLICATION NO. FILING DATE 01/29/2001 Michel Philippe 05725.0834 6832 09/770,473 EXAMINER 11/18/2003 7590 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER YU, GINA C ART UNIT PAPER NUMBER 1300 I STREET, NW WASHINGTON, DC 20005 1617 DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| <del>`</del>   | Application No.         | Applicant(s)                                       |
|--|-------------------------|--|
| •  |                         |  |
| Office Action Summary  | 09/770,473              | PHILIPPE ET AL.                                    |
| Office Action Summary  | Examiner                | Art Unit   |
| The MAILING DATE of this communication app   | Gina C. Yu              | 1617   |
| Period for Reply   |                         |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  |                         |  |
| 1)⊠ Responsive to communication(s) filed on 3.   |                         |  |
| 2a) This action is <b>FINAL</b> . 2b) ☐ This   | action is non-final.    |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |                         |  |
| Disposition of Claims  |                         |  |
| <ul> <li>4) Claim(s) 1-59 is/are pending in the application.</li> <li>4a) Of the above claim(s) 31-59 is/are withdrawn from consideration.</li> <li>5) Claim(s) is/are allowed.</li> <li>6) Claim(s) 1-30 is/are rejected.</li> <li>7) Claim(s) is/are objected to.</li> <li>8) Claim(s) are subject to restriction and/or election requirement.</li> </ul>  |                         |  |
| Application Papers   |                         |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |                         |  |
| Priority under 35 U.S.C. §§ 119 and 120  |                         |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) The translation of the foreign language provisional application has been received.</li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul> |                         |  |
| Attachment(s)  |                         |  |
| Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal F | (PTO-413) Paper No(s) Patent Application (PTO-152) |

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### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2003 has been entered. Claims 1-59 are pending, of which claims 31-59 have been withdrawn from consideration.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph. The specification, while being enabling for the specific skin conditions such as acne, Propionibacterium granulosum, hyperseborrhoea as stated in the specification and dependent claims 2, 3, 7, and 8, applicants' disclosure does not reasonably provide enablement for all "disorders associated with seborrhea and disorders associated with microorganisms of the genus *Propiobacterium*" as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method of topically applying a compound to treat the recited skin disorders. Examiner notes that all the examples in the applicants' specification and dependent claims indicate that the topical application is realized in the form of a composition. The instant claim 1 however seems to claim a method of applying a compound itself alone on the skin or scalp. The metes and bounds of the scope of the claims are not clear.

Claims 25 recites the limitation "said composition" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

The remaining claims are rejected as based on an indefinite base claim.

### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-9, 11-16, 25-27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (US 5886041).

Yu teaches the use of polyamino acids to treat of skin disorders such as acne.

See abstract. The compositions comprise amphoteric compounds such as dipeptides, tripeptides, and polypeptides. See col. 5, lines 6-15. The reference specifically

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teaches that glycylhistidine is a representative dipeptide useful for the invention. See col. 4, lines 47-57. The

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the Yu composition comprising the polyamino acids such as glycylhistidine to treat acne as suggested by the reference because of an expectation of successfully treating the skin disorder.

2. Claims 1-9, 11-16, 25-27, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Thunemann (US 6395284 B1) in view of Aldrich (1996-1997).

Thunemann teaches the use of poly-L-amino acids such as poly-L-lysine in stabilizing retinoic acid in a composition that is used to treat acne. See example 6. Examiner notes that poly-L-lysine meets the limitation of instant claim 1, formula (I). The reference teaches that poly-L-amino acids are used for the complexation of vitamin A acid. See col. 3, lines 3 – 8. Thunemann fails to teach the molecular weight of poly-L-lysine used in Example 6.

Aldrich teaches that poly-L-lysine having average molecular weight in the range of 1K-70K is commercially available.

Given the general teaching of using poly-L-lysine in an acne treatment composition in Thunemann, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior art such as Aldrich for the commercially available polyamino acids and make and use the Thunemann invention to treat acne.

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## Response to Arguments

Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu Patent Examiner

> SREENI PADMANABHAN SUPERVISORY PATENT EXAMINER

> > 1/17/03